REMARKS

Claims 1-45 are pending in the present Application. Claims 4, 8-17, 25, 31, 37 and 40-43 have been withdrawn from consideration; Claims 3, 18, 24 and 30 have been cancelled, Claims 1, 19, 22, 23, 29, 35, 36, 38 and 39 have been amended, and Claims 46-51 have been added, leaving Claims 1, 2, 5-7, 19-23, 26-29, 32-36, 38, 39 and 44-51 for consideration upon entry of the present Amendment.

Support for the amendments to claims 1, 22, 29, and 36 can be found in claim 18 and in the specification in paragraph [0058].

Support for the amendment to claim 3 can be found in claim 3 itself.

Support for the amendment to claim 23 can be found in claim 23 as filed.

Claims 19, 38 and 39 have been amended merely to change their dependency.

Support for new claims 46-49 can be found in claim 19 as filed.

Support for new claims 50 and 51 can be found in claim 21 as filed.

No new matter has been introduced by these amendments or new claims.

Reconsideration and allowance of the claims are respectfully requested in view of the above amendments and the following remarks.

Information Disclosure Statement

Applicants note that the Examiner has not considered the art submitted in the Information Disclosure Statements filed: November 3, 2003, November 12, 2003, February 5, 2004, April 8, 2004, September 30, 2004, and December 9, 2005. Applicants respectfully request that the art submitted in these Information Disclosure Statements be considered and a fully initialed PTO Form A820 be returned to the Applicants.

Claim Informalities

Claims 3 and 18 have been cancelled.

The Examiner suggests that the status identifiers for claims 7, 38 and 39 are incorrect. Applicant believes that claim 7 has mistakenly been labelled by the Examiner as withdrawn. It is noted that claim 7 is directed to a composition "further comprising" the claimed agents. Claims

38 and 39 define the immune stimulant and the anti-cancer agent and are also pending and not withdrawn as the dependency has been changed to claim 36. Correction is requested.

Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 35 stands rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the construction of claim 35 is non-sequitur insofar as it depends from itself. Claim 35 has been amended to depend from claim 34.

Reconsideration and withdrawal of this rejection are respectfully requested.

Claim Rejections Under 35 U.S.C. § 103(a)

Claims 1-3, 5, 6, 18-24, 26-30, 32-36, 44 and 45 stand rejected under 35 U.S.C. § 103(a), as allegedly unpatentable over Japanese Patent No. JP 09-176011 (machine translation) in view of U.S. Patent No. 6,498,188 to Camden. Applicants respectfully traverse this rejection.

According to the Examiner, JP 09-176011 discloses the use of various flavonoids such as wogonin to treat cancer. In paragraph [0039], for example, this reference does appear to teach the use of wogonin to treat gastric, colon, renal, and prostate cancer cell lines, but does not teach treatment of cancer in a human patient. The flavonoids, including wogonin, however, are not used to treat cancer per se, but instead are used to control the expression of the heat shock protein HSP 27 so that the biosynthesis of that protein is decreased. This allows for more effective thermotherapy, that is, once the heat shock protein level has been reduced, the cancer cells are more susceptible to apoptosis induced by warming. Thus, wogonin is not used to treat cancer, but instead is used to "reinforce the effectiveness of chemotherapy." (paragraph [0041]) It is disclosed in paragraph [0030] to use 0.1-80 wt% of the flavonoid as a synthetic inhibitor. JP 09-176011 does not teach the combination of flavonoids with non-phtytoestrogen anti-cancer agents or immunomodulators.

The Examiner combines JP 09-176011 with U.S. Patent No. 6,498,188 to Camden which teaches carbamate and thiocarbamate compounds used against tumors which have been removed from the human and grown in cell culture. There are no combination therapies shown and, rather than demonstrating that combination therapies work with the disclosed carbamates and

thiocarbamates, Camden simply demonstrates that the carbamates and thiocarbamates disclosed can kill cells.

For an obviousness rejection to be proper, the Examiner must meet the burden of establishing that all elements of the invention are disclosed in the prior art; that the prior art relied upon, or knowledge generally available in the art at the time of the invention, must provide some suggestion or incentive that would have motivated the skilled artisan to modify a reference or combined references. *In re Fine*, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). "A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007). To find obviousness, the Examiner must "identify a reason that would have prompted a person of ordinary skill in the art in the relevant field to combine the elements in the way the claimed new invention does." *Id.*

In order to arrive at the claimed compositions, the Examiner combines JP 09-176011, which teaches the use of phytoestrogens in vitro in cancer cells, with Camden which teaches combination chemotherapies with carbamate and thiocarbamate compounds, and not phytoestrogens. In making the rejection, the Examiner alleges that combination chemotherapies are well-known and relies on Camden for this teaching. The teaching of Camden, however, is limited to the teaching that carbamate and thiocarbamate compounds can be combined with additional chemotherapeutic agents. Camden, as admitted by the Examiner, specifically fails to teach the particular advantage of combining a phytoestrogen with an anti-cancer agent and/or an immune stimulant. There is no teaching in the cited references of any advantage of combining phytoestrogens with additional chemotherapeutic agents. Thus, one important difference between the present claims and the cited references is that the cited references do not suggest any advantage of combining phytoestrogens with an additional chemotherapeutic agent to treat cancer.

Another important difference between the present application and the cited art is that both JP 09-176011 and Camden are concerned with in vitro studies and that there are no human studies to show the advantage of the methods and compositions as in the present application. The inventor of the present application has shown in Example 8 of the present application the efficacy of a composition comprising a phytoestrogen and a non-phytoestrogen anti-cancer agent in the treatment of cancer, specifically prostate cancer. Example 8 shows administration of a composition in capsules

to two elderly volunteer patients diagnosed with prostate cancer. As a measure of the progress of the cancer, the bloodstream level of prostate-specific antigen (PSA), a substance produced by the prostate gland, was measured by standard methods. The results are shown in Table 3. As can be seen from Table 3, a dramatic reduction in PSA levels is observed after 1 and 2 months of treatment with the composition.

As explained in the Rule 1.132 declaration of Dr. Sophie Chen, attached hereto, the tested composition of Example 8 is:

Oridonin (non-phytoestrogen anti-cancer)	6 mg
Baicalin (phytoestrogen)	26 mg
Wogonin (phytoestrogen)	26 mg
Iisoliquiritigenin (phytoestrogen)	26 mg
Alcohol extract from 7 plants*	226 mg
Starch	10 mg

Name of 7 plants: *Dendrantherma morifolium,Ganoderma lucidium, Glycyrrhiza uralensis, Isatis indigotica, Panax pseudo-ginseng, Rabdosia rubescens, Scutellaria baicalensis*

Thus, the combination of at least one phytoestrogen and at least one non-phytoestrogen anti-cancer agent produces a significant and unexpected improvement in patients with prostate cancer.

Regarding dependent claims 44 and 45, neither of the cited references discloses treating is taxol-resistant ovarian cancer. Thus, there is an element of these claims that is not taught by the cited references and the cited references do not render these claims obvious.

Reconsideration and withdrawal of this rejection are respectfully requested.

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and withdrawal of the objection(s) and rejection(s) and allowance of the case are respectfully requested.

If there are any additional charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130.

Respectfully submitted,

CANTOR COLBURN LLP

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Sophie Chen	
Serial No.:	10/647,458	Group Art Unit: 1614
Filed:	August 01, 2003	Examiner: Frederick Crass
For:	BOTANICAL EXTRACT COMPOSITIONS AND METHODS OF USE	

DECLARATION PURSUANT TO 37 C.F.R.§1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Sophie Chen, the inventor of the above-referenced application, declares and says:

1. I, Sophie Chen, declare and say that I am the inventor in the above-referenced application ("the '458 application").

2. I obtained my Ph.D. Degree in physical chemistry from Columbia University. I have held many positions, including at Merck Sharp and Dohme as a senior Biophysicist. From July 2007 – present, I have been working at Ovarian and Prostate Cancer Research Trust Laboratory as the research director.

3. I have read and am familiar with the Office Action mailed November 16, 2007.

4. In the '458 application as filed, Example 8 shows administration of a composition in capsules to two elderly volunteer patients diagnosed with prostate cancer. As a measure of the progress of the cancer, the bloodstream level of prostate-specific

antigen (PSA), a substance produced by the malignant prostate gland, was measured by standard methods. The results are shown in Table 3. As can be seen from table 3, a significant reduction in PSA levels is observed after 1 and 2 months of treatment with the composition.

The tested composition is:

Composition (mg/capsule)

Oridonin (anti-cancer)	6 mg
Baicalin (phytoestrogen)	26 mg
Wogonin (phytoestrogen)	26 mg
Isoliquiritigenin (phytoestrogen)	26 mg
Extract from 7 plants*	226 mg
Starch	10 mg

Name of 7 plants: *Dendrantherma morifolium, Ganoderma lucidium, Glycyrrhiza uralensis, Isatis indigotica, Panax pseudo-ginseng, Rabdosia rubescens, Scutellaria baicalensis*

Thus, the combination of at least one phytoestrogen and at least one non-phytoestrogen anti-cancer agent produces a significant and unexpected improvement in patients with prostate cancer.

5. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or document or any patent resulting therefrom.

Date: May 15, 2008

Sophie Chen